

AMENDMENTS TO THE CLAIMS

In the Claims:

Claims 1-38 (Canceled).

39. (Previously presented). A process for the manufacture of a vaccine composition comprising admixing a) an adjuvant composition containing an immunostimulant adsorbed onto a first metallic salt particle substantially free of antigen, and b) an antigen.

40. (Previously presented). The process of claim 39, wherein the antigen is adsorbed onto a second metallic salt particle substantially free of antigen, wherein the metallic salt of each of the first metallic salt particle and the second metallic salt particle may be the same.

41. (Previously presented). A process for the manufacture of an immunogenic composition comprising admixing a) an adjuvant composition containing an immunostimulant adsorbed onto a first metallic salt particle substantially free of antigen, and b) an antigen, wherein the antigen of b) elicits an immune response to a pathogen, polypeptide, or anti-tumour antigen selected from the group consisting of antigens derived from Human Immunodeficiency Virus, Varicella Zoster virus, Herpes Simplex Virus type 1, Herpes Simplex Virus type 2, Human cytomegalovirus, Dengue virus, Hepatitis A, B, C or E, Respiratory Syncytial virus, human papilloma virus, Influenza virus, *Haemophilus influenzae* Type B ("Hib"), Meningitis virus, Salmonella, Neisseria, Borrelia, Chlamydia, Bordetella, Plasmodium or Toxoplasma, IgE peptides, Der p1, pollen related antigens; or Tumor associated antigens (TAA), MAGE, BAGE, GAGE, MUC-1, Her-2 neu, luteinizing hormone-releasing hormone (gonadotropin-releasing hormone), CEA, PSA, KSA, and PRAME.

42. (Previously presented). A vaccine composition comprising an adjuvant composition and an antigen, wherein the adjuvant composition contains an immunostimulant adsorbed onto a metallic salt particle, wherein the metallic salt particle is substantially free of the antigen and wherein the immunostimulant is selected from the

group consisting of monophosphoryl lipid A, derivatives thereof, an immunostimulatory nucleotide, and an immunostimulatory cytokine.

43.-45. (Canceled).

46. (Previously presented). A vaccine composition comprising two major populations of complexes, (a) a first complex containing an immunostimulant adsorbed onto a metallic salt particle which is substantially free of antigen; and (b) a second complex containing antigen adsorbed onto a metallic salt particle which is optionally substantially free of immunostimulant; wherein the metallic salt from the first complex may be identical to or different from the metallic salt of the second complex.

47. (Canceled).

48. (Previously presented). The vaccine composition of claims 46, wherein the metallic salt present in the first and second complexes are identical.

49. (Previously presented). The vaccine composition of claim 46, wherein the second complex contains a plurality of sub-complexes, each sub-complex containing ~~a different~~ an antigen adsorbed onto a metallic salt particle wherein each sub-complex contains a different antigen.

50. (Currently Amended). The vaccine composition of claim ~~44~~, 46 wherein the metallic salt is a salt of aluminum, zinc, calcium, cerium, chromium, iron, or beryllium.

51. (Previously presented). The vaccine composition of claim 50 wherein the metallic salt is a phosphate or hydroxide.

52. (Previously presented). The vaccine composition of claim 51 wherein the metallic salt is aluminium hydroxide or aluminium phosphate.

53. (Previously presented). The vaccine composition of claim 42, wherein the immunostimulant is 3-de-O-acylated monophosphoryl lipid A.

54.-55. (Canceled).

56. (Previously presented). The vaccine composition of claim 46, wherein the immunostimulant is 3-de-O-acylated monophosphoryl lipid A.

57. (Canceled).

58. (Previously presented). The vaccine composition of claim 48, wherein the immunostimulant is 3-de-O-acylated monophosphoryl lipid A.

59. (Previously presented). The vaccine composition of claim 49, wherein the immunostimulant is 3-de-O-acylated monophosphoryl lipid A.

60. (Previously presented). The vaccine composition of claim 50, wherein the immunostimulant is 3-de-O-acylated monophosphoryl lipid A.

61. (Previously presented). The vaccine composition of claim 51, wherein the immunostimulant is 3-de-O-acylated monophosphoryl lipid A.

62. (Previously presented) The vaccine composition of claim 52, wherein the immunostimulant is 3-de-O-acylated monophosphoryl lipid A.

63-70 (Canceled).

71. (Previously presented). The immunogenic composition of claim 127, wherein the antigen elicits an immune response against a pathogen, polypeptide, or anti-tumour antigen selected from the group consisting of: Human Immunodeficiency Virus, Varicella Zoster virus, Herpes Simplex Virus type 1, Herpes Simplex virus type 2, Human

cytomegalovirus, Dengue virus, Hepatitis A, B, C or E, Respiratory Syncytial virus, Human papilloma virus, Influenza virus, *Haemophilus influenzae* Type B ("Hib"), Meningitis virus, Salmonella, Neisseria, Borrelia, Chlamydia, Bordetella, Plasmodium or Toxoplasma, stanworth decapeptide, Der p1, pollen related antigens; or cancer associated antigens, MAGE, BAGE, GAGE, MUC-1, Her-2 neu, luteinizing hormone-releasing hormone (gonadotropin-releasing hormone), CEA, PSA, tyrosinase, Survivin, KSA, PRAME, RTS,S, *P. faciparum* MSP1, *P. faciparum* AMA1, *P. faciparum* MSP3, *P. faciparum* EBA, *P. faciparum* GLURP, *P. faciparum* RAP1, *P. faciparum* RAP2, *P. faciparum* Sequestrin, *P. faciparum* PfEMP1, *P. faciparum* Pf332, *P. faciparum* LSA1, *P. faciparum* LSA3, *P. faciparum* STARP, *P. faciparum* SALSA, *P. faciparum* PfEXPa, *P. faciparum* Pfs25, *P. faciparum* Pfs28, *P. faciparum* PFS27/25, *P. faciparum* Pfs16, *P. faciparum* Pfs48/45, *P. faciparum* Pfs230, and any analogues of *P. faciparum* antigens from *Plasmodium* spp.

72-74.(Canceled).

75. (Previously presented). The immunogenic composition of claim 131, wherein the antigen elicits an immune response against a pathogen, polypeptide, or anti-tumour antigen selected from the group consisting of: Human Immunodeficiency Virus, Varicella Zoster virus, Herpes Simplex Virus type 1, Herpes Simplex virus type 2, Human cytomegalovirus, Dengue virus, Hepatitis A, B, C or E, Respiratory Syncytial virus, Human papilloma virus, Influenza virus, *Haemophilus influenzae* Type B ("Hib"), Meningitis virus, Salmonella, Neisseria, Borrelia, Chlamydia, Bordetella, Plasmodium or Toxoplasma, stanworth decapeptide, Der p1, pollen related antigens; or cancer associated antigens, MAGE, BAGE, GAGE, MUC-1, Her-2 neu, luteinizing hormone-releasing hormone (gonadotropin-releasing hormone), CEA, PSA, tyrosinase, Survivin, KSA, PRAME, RTS,S, *P. faciparum* MSP1, *P. faciparum* AMA1, *P. faciparum* MSP3, *P. faciparum* EBA, *P. faciparum* GLURP, *P. faciparum* RAP1, *P. faciparum* RAP2, *P. faciparum* Sequestrin, *P. faciparum* PfEMP1, *P. faciparum* Pf332, *P. faciparum* LSA1, *P. faciparum* LSA3, *P. faciparum* STARP, *P. faciparum* SALSA, *P. faciparum* PfEXPa, *P. faciparum* Pfs25, *P. faciparum* Pfs28, *P.*

faciparum PFS27/25, *P. faciparum* Pfs16, *P. faciparum* Pfs48/45, *P. faciparum* Pfs230, and any analogues of *P. faciparum* antigens from *Plasmodium* ssp.

76. (Canceled).

77. (Previously presented). The immunogenic composition of claim 133, wherein the antigen elicits an immune response against a pathogen, polypeptide, or anti-tumour antigen selected from the group consisting of: Human Immunodeficiency Virus, Varicella Zoster virus, Herpes Simplex Virus type 1, Herpes Simplex virus type 2, Human cytomegalovirus, Dengue virus, Hepatitis A, B, C or E, Respiratory Syncytial virus, Human papilloma virus, Influenza virus, *Haemophilus influenzae* Type B ("Hib"), Meningitis virus, Salmonella, Neisseria, Borrelia, Chlamydia, Bordetella, Plasmodium or Toxoplasma, stanworth decapeptide, Der p1, pollen related antigens; or cancer associated antigens, MAGE, BAGE, GAGE, MUC-1, Her-2 neu, luteinizing hormone-releasing hormone (gonadotropin-releasing hormone), CEA, PSA, tyrosinase, Survivin, KSA, PRAME, RTS,S, *P. faciparum* MSP1, *P. faciparum* AMA1, *P. faciparum* MSP3, *P. faciparum* EBA, *P. faciparum* GLURP, *P. faciparum* RAP1, *P. faciparum* RAP2, *P. faciparum* Sequestrin, *P. faciparum* PfEMP1, *P. faciparum* Pf332, *P. faciparum* LSA1, *P. faciparum* LSA3, *P. faciparum* STARP, *P. faciparum* SALSA, *P. faciparum* PfEXPa, *P. faciparum* Pfs25, *P. faciparum* Pfs28, *P. faciparum* PFS27/25, *P. faciparum* Pfs16, *P. faciparum* Pfs48/45, *P. faciparum* Pfs230, and any analogues of *P. faciparum* antigens from *Plasmodium* ssp.

78. (Previously presented). The immunogenic composition of claim 134, wherein the antigen elicits an immune response against a pathogen, polypeptide, or anti-tumour antigen selected from the group consisting of: Human Immunodeficiency Virus, Varicella Zoster virus, Herpes Simplex Virus type 1, Herpes Simplex virus type 2, Human cytomegalovirus, Dengue virus, Hepatitis A, B, C or E, Respiratory Syncytial virus, Human papilloma virus, Influenza virus, *Haemophilus influenzae* Type B ("Hib"), Meningitis virus, Salmonella, Neisseria, Borrelia,

Chlamydia, Bordetella, Plasmodium or Toxoplasma, stanworth decapeptide, Der p1, pollen related antigens; or cancer associated antigens, MAGE, BAGE, GAGE, MUC-1, Her-2 neu, luteinizing hormone-releasing hormone (gonadotropin-releasing hormone), CEA, PSA, tyrosinase, Survivin, KSA, PRAME, RTS,S, *P. faciparum* MSP1, *P. faciparum* AMA1, *P. faciparum* MSP3, *P. faciparum* EBA, *P. faciparum* GLURP, *P. faciparum* RAP1, *P. faciparum* RAP2, *P. faciparum* Sequestrin, *P. faciparum* PfEMP1, *P. faciparum* Pf332, *P. faciparum* LSA1, *P. faciparum* LSA3, *P. faciparum* STARP, *P. faciparum* SALSA, *P. faciparum* PfEXPa, *P. faciparum* Pfs25, *P. faciparum* Pfs28, *P. faciparum* PFS27/25, *P. faciparum* Pfs16, *P. faciparum* Pfs48/45, *P. faciparum* Pfs230, and any analogues of *P. faciparum* antigens from *Plasmodium* ssp.

79 -81 (Canceled)

82. (Previously presented). The vaccine composition of claim 42, wherein the antigen is a combination of Hepatitis A antigen and Hepatitis B antigen.

83- 85 (Canceled).

86. (Previously presented). The vaccine composition -of claim 46, wherein the antigen is a combination of Hepatitis A antigen and Hepatitis B antigen.

87. (Canceled).

88. (Previously presented). The vaccine composition of claim 48, wherein the antigen is a combination of Hepatitis A antigen and Hepatitis B antigen.

89. (Previously presented). The vaccine composition of claim 49, wherein the antigen is a combination of Hepatitis A antigen and Hepatitis B antigen.

90. (Previously presented). The vaccine composition of claim 50, wherein the antigen is a combination of Hepatitis A antigen and Hepatitis B antigen.

91. (Previously presented). The vaccine composition of claim 51, wherein the antigen is a combination of Hepatitis A antigen and Hepatitis B antigen.

92. (Previously presented). The vaccine composition of claim 52, wherein the antigen is a combination of Hepatitis A antigen and Hepatitis B antigen.

93. (Previously presented). The vaccine composition of claim 42, wherein the antigen is RTS,S.

94 -96 (Canceled)

97. (Previously presented). The vaccine composition of claim 46, wherein the antigen is RTS,S.

98. (Canceled).

99. (Previously presented). The vaccine composition of claim 48, wherein the antigen is RTS,S.

100. (Previously presented). The vaccine composition of claim 49, wherein the antigen is RTS,S.

101. (Previously presented). The vaccine composition of claim 50, wherein the antigen is RTS,S.

102. (Previously presented). The vaccine composition of claim 51, wherein the antigen is RTS,S.

103. (Previously presented). The vaccine composition of claim 52, wherein the antigen is RTS,S.

104. (Previously presented). A method of treating a mammal suffering from or susceptible to a pathogenic infection, or cancer, or allergy, comprising the administration of a safe and effective amount of the vaccine composition of claim 42.

105- 107. (Canceled).

108. (Previously presented). A method of treating a mammal suffering from or susceptible to a pathogenic infection, or cancer, or allergy, comprising the administration of a safe and effective amount of the vaccine composition of claim 46.

109. (Canceled).

110. (Previously presented). A method of treating a mammal suffering from or susceptible to a pathogenic infection, or cancer, or allergy, comprising the administration of a safe and effective amount of the vaccine composition of claim 48.

111. (Previously presented). A method of treating a mammal suffering from or susceptible to a pathogenic infection, or cancer, or allergy, comprising the administration of a safe and effective amount of the vaccine composition of claim 49.

112. (Previously presented). A method of treating a mammal suffering from or susceptible to a pathogenic infection, or cancer, or allergy, comprising the administration of a safe and effective amount of the vaccine composition of claim 50.

113. (Previously presented). A method of treating a mammal suffering from or susceptible to a pathogenic infection, or cancer, or allergy, comprising the administration of a safe and effective amount of the vaccine composition of claim 51.

114. (Previously presented). A method of treating a mammal suffering from or susceptible to a pathogenic infection, or cancer, or allergy, comprising the administration of a safe and effective amount of the vaccine composition of claim 52.

115. (Canceled).

116. (Previously presented). A vaccine composition comprising: a) an immunostimulant adsorbed onto a metallic salt particle, wherein the immunostimulant is selected from the group consisting of bacterially derived compounds, monophosphoryl lipid A, immunostimulatory oligonucleotides, CpG, block copolymers, cholera toxin, immunostimulatory cytokines, GM-CSF, IL-1, polyriboA, polyriboU, and Muramyl tripeptide, and b) an antigen, wherein the antigen is not adsorbed onto the metallic salt particle.

117-119. (Canceled).

120. (Previously presented). The process of claim 41, wherein the antigen elicits an immune response to human papilloma virus (HPV).

121. (Previously presented). The process of claim 120, wherein the HPV is selected from the group consisting of: HPV 6, HPV 11, HPV 16 and HPV 18.

122. (Previously presented). The process of claim 120, wherein the antigen is an L1 particle or capsomer.

123. (Previously presented). The vaccine of claim 42 wherein the antigen elicits an immune response to human papilloma virus (HPV).

124. (Previously presented). The vaccine composition according to claim 123, wherein the HPV is selected from the group of: HPV 6, HPV 11, HPV 16 and HPV 18.

125. (Previously presented). The vaccine composition of claim 123, wherein the antigen is an L1 particle or capsomer.

126. (Canceled).

127. (Previously presented). An immunogenic composition comprising an adjuvant composition; and an antigen, wherein the adjuvant composition contains an immunostimulant adsorbed onto a metallic salt particle, wherein the metallic salt particle is substantially free of the antigen and wherein the immunostimulant is selected from the group consisting of monophosphoryl lipid A, derivatives thereof, an immunostimulatory nucleotide, and an immunostimulatory cytokine.

128-130. (Canceled).

131. (Previously presented). An immunogenic composition comprising two populations of complexes, a first complex comprising, (a) a first complex containing an immunostimulant adsorbed onto a metallic salt particle which is substantially free of antigen; and (b) a second complex containing antigen adsorbed onto a metallic salt particle which is optionally substantially free of immunostimulant; wherein the metallic salt from the first complex may be identical to or different from the metallic salt of the second complex.

132. (Canceled).

133. (Previously presented). The immunogenic composition of claim 131, wherein the metallic salt present in the first complex is identical to the metallic salt present in the second complex.

134. (Previously presented). The immunogenic composition of claim 131, wherein the second complex contains a plurality of sub-complexes, each sub-complex containing an

Application No. 10/031,261
Attorney Docket No. PG3694USW

antigen adsorbed onto a metallic salt particle wherein each sub-complex contains a different antigen.

135-141. (Canceled).